

C.S. A3: Observational Study Using Provider Interviews and Questionnaires

C.S. A3.2: Provider Interviews and Questionnaires for Obtaining Data on Organizational Characteristics

Overview

This study will use provider interviews and written surveys to assess how a new clinical reminder system is working at 8 VAMCs.

Subjects and Sample Size

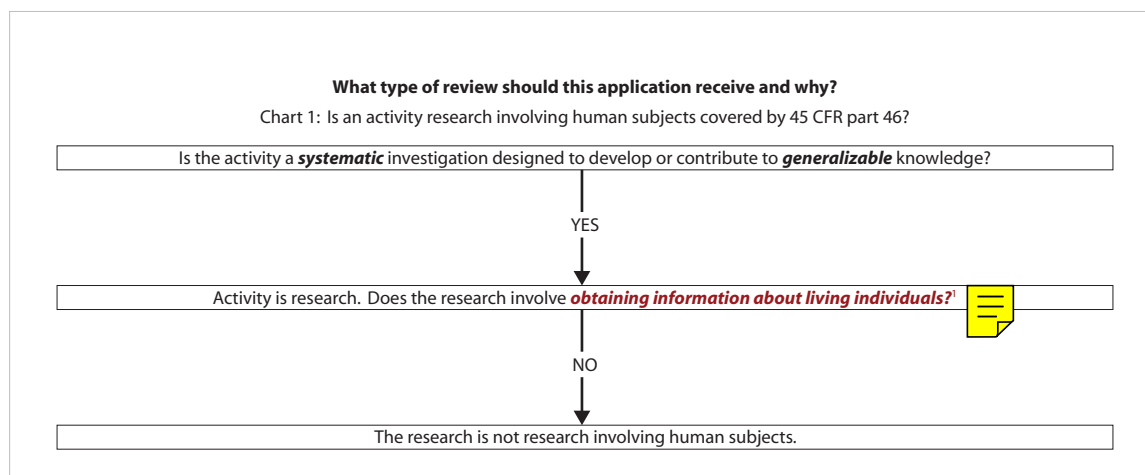
The subjects are 70 VA primary care physicians at 8 VAMCs.

Data Collection

Data collected will include information on how providers were educated in the use of the clinical reminder system, and data about organizational structure. The providers will not be

asked about their satisfaction with the system or their opinions on how the system could be improved. Data are confidential, but are not anonymous since providers are interviewed in person and data from interviews and surveys must be linked. The crosswalk file linking provider identifying data to study identification numbers will be maintained as a separate file, in a password-protected drive that is separate from the drive containing the study data. No study data will be maintained with the provider identifying data.

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[From OHRP Web site: www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm]**Notes for C.S. A3.2**

¹**Discussion:** The majority of the panel members felt that the questions are not eliciting personal information or opinions. Under this scenario, the thing that is being researched is organizational structure and processes, not human subjects. Human beings are involved as a way of obtaining the desired information, but they are not the focus of the research, and there is no added value from trying to protect them under human subjects review.

Five panel members disagreed with the majority, and felt that as long as human beings are being asked the questions, and they have the opportunity to put their own interpretation on the responses, then human beings are being

studied. Only organizational data collected from reports or databases do not involve human subjects. However, even in the latter case, if an organization is being evaluated, and the organization consists of human subjects, then this is human subjects research.

In determining whether or not this case should be considered human subjects research, one panel member said it would depend on whether or not data on provider characteristics are being collected. If such data are being collected, then this means human beings are being studied, because the investigator is interested in looking at how the responses vary by provider characteristic.